DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

4092 '99 MAY -4 A10:10

APR 29 1999

Re: GenESA®
Docket No.: 98E-0319

The Honorable Q. Todd Dickinson
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Box Pat. Ext.
Assistant Commissioner for Patents
Washington, DC 20231

Dear Commissioner Dickinson:

This is in regard to the application for patent term extension for U.S. Patent No. 5,234,404, filed by Gensia Sicor, Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the application and have determined the regulatory review period for GenESA®, the human drug product claimed by the patent.

The total length of the regulatory review period for GenESA® is 2,641 days. Of this time, 1,295 days occurred during the testing phase and 1,346 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: June 22, 1990.

   The applicant claims June 23, 1990, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was June 22, 1990, which was thirty days after FDA receipt of the IND.

2. The date the application was initially submitted with respect to the human drug product under section 505 of the Federal Food, Drug, and Cosmetic Act: January 6, 1994.

   The applicant claims December 21, 1993, as the date the new drug application (NDA) for GenESA® (NDA 20-420) was initially submitted. However, FDA records indicate that NDA 20-420 was submitted on January 6, 1994.

3. The date the application was approved: September 12, 1997.

   FDA has verified the applicant's claim that NDA 20-420 was approved on September 12, 1997.

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This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Thomas J. McGinnis, R.Ph.
Deputy Associate Commissioner
for Health Affairs

cc: Jessica Wolff
Lyon & Lyon LLP
Suite 660
4250 Executive Square
La Jolla, CA 92037

DATE: APR 2 9 1999

TO: Sabrina Crisp, Regulations Policy and Management Staff, HF-26

From: Brian J. Malkin, Associate Director for Patents and Hearings, HFY-20

RE: Federal Register Notice Information for GenESA®
Docket No. 98E-0319, FRDTS# OC99115

Attached is a FR Notice for the human drug product, GenESA®. This document has been internally reviewed and cleared by OHA.

Please note that GenESA® is a registered trademark. Therefore, the superscript "R" notation will be needed.

Please call me if you have any questions. My number is 827-6620 (Rm. 15-22).

Thank you for your assistance.

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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

2507 '99 MAY -4 A9:48

Memorandum

Date: APR 29 1999

From: Brian J. Malkin, Associate Director for Patents and Hearings
Health Assessment Policy Staff (HFY-20)

Subject: Patent Term Restoration Application
for GenESA®

To: Dockets Management (HFA-305)

Attached is a letter to the Patent Term Office for the above mentioned human drug product under the Docket Number **98E-0319** stating that this particular patent is eligible for regulatory review. The Patent Number is **5,234,404**. Please place this recent correspondence in the appropriate file.

If you have any questions, please contact me at 827-6620. Thank you for your assistance.